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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,034	02/09/2004	Stephanie M. Kladakis	022956-0260	6915
21125 7590 07/29/2009 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
NOTIFICATION DATE		DELIVERY MODE		
07/29/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary**Application No.**

10/775,034

Applicant(s)

KLADAKIS ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9,10,13-18,20,21,24-28,30-39 and 42-53 is/are pending in the application.
- 4a) Of the above claim(s) 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,10,13-18,20,21,24-28,30,31,34-39 and 42-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-6,9,10,13-18,20,21,24-28,30,31,34-39,42-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke et al. (6005161). Brekke et al. disclose (Figs. 1-4) a porous tissue scaffold formed of a bioresorbable, synthetic polymer, col. 5, lines 6-15. It can be seen the implant comprises at least one pocket or void, col. 7, lines 37-40. Brekke discloses the pockets or voids *comprise* cells *and* viable tissue that is ground (Examiner interprets as minced) with the cells capable of migrating into the scaffold's structure, col. 10, lines 19-21,42-47. The voids cause the implant to have hollow interior sections or lumens. The cells are used with growth factors to enhance their reproduction to form their extracellular matrix in the scaffolds, Col. 10, lines 31-37. Brekke additionally teaches to use harvested tissue, col. 10, lines 54-67. Common sense would be used in harvesting the tissue in that the surgeon, doctor or specialist would remove healthy tissue to form or provide the grafting material. No doctor, surgeon or specialist would use diseased tissue on a patient and risk the possibility of causing the patient more harm. However, Brekke et al. do not explicitly state the shape of the implant is "wedge-shaped". It is noted that Brekke does teach the device can be wedged into the defect or cavity of repair, see abstract. It would have been obvious to one of ordinary skill in the art to modify the shape to be "wedge-shape"

since such a modification only involves routine skill in the art. A change in shape or form is recognized as being within the skill of a normal artisan in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47. Regarding claims 3,4,15,16,25,26,36,37 Brekke discloses the implant can include a bioactive substance such as cartilage Proteins, col. 10, lines 17-41. With respect to claims 5,6,17,18,27,28 any 3-dimensional object inherently has top and bottom portions which are arbitrary. The porous scaffold has an internetwork to connect the portions. Cells of the native tissue are capable of populating the scaffold. Regarding claims 13,34 Brekke discloses the tissue placed in the "pocket" or voids can be construed to be either minced, sliced or slivered, col. 6, lines 1-4, col. 10, lines 13,14. Regarding claim 24, Figs. 5,6 show the step of loading viable tissue into the pockets of the tissue scaffold. Brekke discloses the step of implanting, col. 12, line 3.

With respect to claims 44, 45,50,51 Brekke does disclose the tissue size can be optimized to the desired need of the patient, col. 11, lines 14-15. It would have been obvious to one of ordinary skill in the art to find the optimal size of the tissue fragments to be used in the composite implant. Thus, it would have been an obvious expedient to have a thickness range of 200 μ m to 3mm for the tissue fragments or a particle size in the range of 0.5mm³ to about 3 mm³ since such a modification only involves routine skill in the art absent a showing of unexpected results.

Claims 1, 3-6,9,10,13-18,20,21,42-47 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, claims 1,3-6,9,10,13-18,20,21,24-28,30,31,34-39,42-53 are rejected under 35 U.S.C. 103(a) as obvious over Schwartz et al.

(2003/78617). Please note the Examiner is interpreting claims 1,13 as product-by-process claims including the limitation of "harvested from healthy tissue." In an ex parte case product-by-process claims are not construed as being limited to the product formed by the specific processes recited. In re Hirao, 535 F2d 67, 190 U.S.P.Q. 15 see footnote 3 (CCPA 1976). Clearly one of skill in the art would harvest tissue from a healthy organ, bone, soft tissue or other areas of the body to obtain graft material. A surgeon or doctor with common sense would not graft diseased tissue to use in a patient and risk the unsuccessful result of not repairing the defect because of using diseased tissue. Thus, the tissue obtained in the Schwartz device is fully capable of being harvested from "healthy tissue." Fig. 17 shows a wedge-shaped tissue scaffold. Schwartz et al. disclose the tissue repair device comprises a porous resorbable material, paragraphs 16,17. Schwartz also discloses the material can be synthetic, paragraphs 83,86,94. It can be seen the implant includes top and bottom portions **24,26** respectively. Fig. 34 illustrates the top and bottom portions can be mated to one another. Schwartz discloses the implant pocket material can be an ECM. The examiner is interpreting the claimed elements "viable tissue" in this way: capable of working or being used. Claims in a pending application should be given *their broadest reasonable interpretation*. In re Pearson, 181 USPQ 641 (CCPA 1974). See also In re Morris, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Since Schwartz discloses material that is fully capable of being used and working in the body to repair the defect, it is viable. Schwartz additionally shows (Fig. 23) that there is a tissue material **22** placed in a pocket or hollow interior or lumen that extends from the greater height to the tapered smaller end

and is formed between the top and bottom portions. Bioactive substances can be added to the tissue material, paragraphs 130,131. Schwartz et al. disclose that tissue is obtained and comminuted (i.e. minced) to smaller fragments and then loaded between or within the pocket of the tissue scaffold, paragraphs 16,17,83. Schwartz et al. disclose that osteoblasts are one type of cells placed therein, paragraph 133. Budny (2005/147645) teaches that an ECM provides the necessary framework for cell migration, such as osteoblasts, paragraph 25. Thus, it is inherent that the cells of Schwartz's implantable device migrate into the scaffold. Upon migration and repopulation of the scaffold, it is known that when cells regenerate they form their extracellular matrix. Figs. 26 and 31 show the implantation is done such that native tissue 12 abuts the opening of the pocket to maintain the tissue 22 therein. Regarding claims 42,43,46-49,52,53 since the ECM 21 covers a portion of the native tissue 12 (Fig. 19) it can be construed that the cells populate a portion of the scaffold and cells from the native tissue populate a portion of the scaffold that lie beneath that portion of the scaffold. With respect to claims 44,50 Schwartz discloses the size of the fragment or tissue can be about 200µm, paragraph 122.

Regarding claims 24-28,30,31,34-39,42-53, it is noted that Schwartz et al. do not explicitly state the viable tissue is obtained from that harvested from healthy tissue. Clearly the ability to obtain healthy tissue for use as graft material is recognized as part of the skill and ordinary capabilities of one skilled in the art. Finding healthy tissue for use as tissue repair material would have been the objective for a doctor treating a patient needing treatment. The doctor clearly would determine that the tissue harvested

from the donor is healthy and suitable to treat a patient in need of repair of a defect. It would have been obvious to one of ordinary skill in the art to find healthy tissue and use it for the viable tissue to be placed in the pocket of the tissue scaffold of Schwartz's device to increase the suitability of the implant placed in the patient by providing the predictable result of using a non-disease transmitting material in the patient.

With respect to claims 45,51, it is noted that Schwartz does disclose that the particle size can be any dimension and is not to be limited to particular dimensions, paragraph 122. However, Schwartz fails to explicitly disclose the tissue fragments are of a particle size having the dimension of 0.5 mm^3 to 3 mm^3 . It would have been obvious to one of ordinary skill in the art to utilize a particle dimension as claimed since such a modification only involves routine skill in the art and varying the size would not affect the function of the cells to carry out a process.

Response to Arguments

Applicant's arguments filed 4/9/09 have been fully considered but they are not persuasive. Applicants argue that the Brekke reference does not teach viable tissue comprising naturally occurring cells and their extracellular matrix and the viable tissue is minced to form finely minced tissue fragments. MPEP 2111.03 states the transitional term "**comprising**", is inclusive or open-ended and does not exclude additional, unrecited elements. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004). "Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may

be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Applicants focus on the teachings of Brekke suggesting the cells are harvested and a tissue is attached to the scaffold. However, what needs to be considered is what the claims do recite. It must be noted that the claims do not exclude the fact that the tissue can be cells in combination with ground up or minced tissue material. Therefore, Brekke can be said to comprise viable tissue that includes cells that can migrate and also include mince tissue fragments.

Applicants argue that the Schwartz reference does not teach cells and their extracellular matrix. However, first it is noted that naturally occurring cells are used in the implantable scaffold of Schwartz and thus these cells clearly migrate and populate the scaffold. Second since they are living cells they clearly are populating the scaffold and regenerating their extracellular matrix. Schwartz clearly discloses the proper conditions and cellular components to promote cell viability, paragraphs 131-134. With respect to the viable tissue that is minced and the argument that Applicants suggest Schwartz does not contain mince tissue. The Examiner respectfully disagrees since clearly it can be interpreted that comminuted or chopped up tissue is considered minced and since ECM is a naturally occurring material, it is viable tissue. Thus, Schwartz discloses such tissue. To reiterate the claim scope presented in the pending claims, the same interpretation can be applied against the claims in regards to the Schwartz

reference that since the claims use "comprising" it can be said the composite scaffold includes cells and minced tissue. The transition phrase does not exclude the use of other elements in combination.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738